

## **REMARKS**

Favorable reconsideration is respectfully requested.

The claims are 1 to 21.

The above amendment is responsive to points set forth in the Official Action.

### **I. Status of the Claims**

Claim 22 has been canceled without prejudice. Claims 1 and 2 have been amended to clarify the solvate forms of the compound of formula (I). Claims 4 to 5 and 8 to 11 have been amended as requested by the Examiner to present the X-ray data in proper form. Claims 6, 12, 14, 18, 19 and 21 have been amended to clarify the claimed subject matter and to correct typographical errors. Claims 13, 20 and 21 have been amended to recite "n-hexane or n-heptane" as the solvent for recrystallization. Support for the claim amendments may be found, for example, in the specification at paragraphs [0019], [0020], [0022], [0024], [0040], [0061] and [0063] and in the original claims. No new matter has been added.

Claims 1 to 21 are pending in this application. Applicants thank the Examiner for indicating that claims 3, 6, 7, 12, 13, 18 and 21 would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claim.

### **II. Information Disclosure Statement**

The Examiner has not reviewed several references previously submitted because only the first page of each reference was provided. Applicants apologize for this oversight. Submitted herewith are full copies of each of the references with an Information Disclosure Statement and Form PTO-1449. The Examiner is respectfully requested to review these references and to initial and return the accompanying Form PTO-1449 to confirm that they have been fully considered.

### **III. The Rejections Under 35 U.S.C. §112**

(i) Claims 1 to 2, 14 to 17 and 19 to 20 have been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The rejection asserts that the specification is enabling for ethyl acetate and butyl acetate solvates of the compound of formula (I), but asserts that it is not enabling for the base compound or any salts or other solvates. The rejection concludes that because the base compound is non-crystalline, it is clear that not all forms are crystalline.

Claim 1 does not encompass the base compound of formula (I), or salts thereof. Rather, claim 1 has been amended to recite specific crystalline solvates, namely hydrates, alcoholates, etherates and solvates formed with an ester solvent. Paragraph [0023] of the specification lists specific examples of each of these classes of solvents. The specification clearly discloses, at paragraphs [0015], [0022], [0059] and [0060] how the claimed crystalline solvates can be prepared.

The test for enablement is not whether any experimentation is needed but whether or not that experimentation is undue. See, *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976). Even a considerable amount of experimentation, or complex experimentation, is permissible if it is routine. See e.g. *Ex parte Jackson*, 217 USPQ 804, 807 (POBA 1982) and *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988). As shown above, Applicants' disclosure provides more than sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention with no more than routine experimentation.

In view of the above remarks, Applicants believe that claims 1 to 21 are fully enabled by the specification. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

(ii) Claim 22 been rejected under 35 U.S.C. §112, second paragraph, as indefinite. Claim 22 has been canceled, rendering this rejection moot.

### **IV. The Rejection Under 35 U.S.C. §101**

Claim 22 been rejected under 35 U.S.C. §101. Claim 22 has been canceled, rendering this rejection moot.

**V. Conclusions**


In view of the comments and amendments set forth above, each of the presently pending claims in this application is believed to be in immediate condition for allowance.

No further issues remaining, allowance of this application is respectfully requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact undersigned at the telephone number below.

Respectfully submitted,

Kazuhiro AIHARA et al.

By:   
Matthew M. Jacob  
Registration No. 25,154  
Attorney for Applicants

MJ/aas  
Washington, D.C. 20006-1021  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
July 17, 2008